

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A composition, comprising:

a very low water-soluble drug; and

a porous silicon material;

wherein:

the composition is produced by treating a mixture comprising the very low water-soluble drug and the porous silicon material with a supercritical or subcritical carbon dioxide fluid;

the very low water-soluble drug has a solubility in water at 25 °C of less than 10 µg/mL prior to treatment;

the porous silicon material comprises light anhydrous silicic acid, hydrated silicon dioxide, silicon dioxide, or calcium silicate;

the porous silicon material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of  $\pm 40\%$  of the average pore diameter accounts for 60% or more of a volume of all of the pores of the porous silica material, and having an X-ray diffraction pattern including one or more peaks at a diffraction angle ( $2\theta$ ) corresponding to d of 1 nm or more;

the porous silicon material has an average pore diameter of 1 to 500 nm; ~~and~~

the porous silicon material has a specific surface area of 100 to 1,800 m<sup>2</sup>/g; ~~and~~

the composition is suitable for oral administration.

Claims 2-6 (Cancelled).

Claim 7 (Currently Amended): The composition according to ~~any one of claims 1 through 4~~claim 1, wherein the porous silicon material has an average pore diameter of 2 to 200 nm.

Claims 8-9 (Cancelled).

Claim 10 (Currently Amended): The composition according to ~~any one of claims 1 through 4~~claim 1, wherein the porous silicon material has a specific surface area of 200 to 1,500 m<sup>2</sup>/g.

Claim 11 (Currently Amended): The composition according to ~~any one of claims 1 through 4~~claim 1, wherein a ratio by weight of the very low water-soluble drug to the porous silicon material is 1:0.1 to 1:1,000.

Claim 12 (Currently Amended): The composition according to ~~any one of claims 1 through 4~~claim 1, wherein the very low water-soluble drug is 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one or prednisolone valerate acetate.

Claim 13 (Currently Amended): A drug product comprising the composition according to ~~any one of claims 1 through 4~~claim 1.

Claim 14 (Withdrawn – Currently Amended): A method for producing the composition according to claim 1, comprising:

placing ~~a~~the very low water-soluble drug and ~~a~~the porous silicon material in a pressure-resistant vessel;

filling the vessel with carbon dioxide;  
maintaining the vessel at a temperature and pressure such that the carbon dioxide assumes the form of supercritical or subcritical fluid; and  
discharging the carbon dioxide fluid from the vessel and collecting the resultant composition;

wherein:

~~the porous material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of  $\pm$  40% of the average pore diameter accounts for 60% or more of a volume of all the pores of the material, and having an X-ray diffraction pattern including one or more peaks at a diffraction angle ( $2\theta$ ) corresponding to d of 1 nm or more;~~

~~the porous material has an average pore diameter of 1 to 500 nm; and~~

~~the porous material has a specific surface area of 100 to 1,800 m<sup>2</sup>/g.~~

Claim 15 (Withdrawn): The method according to claim 14, wherein a ratio by weight of the very low water-soluble drug to the supercritical or subcritical carbon dioxide fluid is from 1:1 to 1:1,000,000.

Claim 16 (Withdrawn): The method according to claim 14, wherein maintaining the vessel comprises maintaining the vessel at temperature of from  $-40$  to  $100^{\circ}\text{C}$ .

Claim 17 (Withdrawn): The method according to claim 14, wherein maintaining the vessel comprises maintaining the vessel at a pressure of from 1 to 50 MPa.

Claim 18 (Withdrawn – Currently Amended): The method according to claim 14, wherein the very low water-soluble drug and porous silicon material are maintained in contact with the supercritical or subcritical carbon dioxide fluid for a period of from one minute to 24 hours.

Claim 19 (Withdrawn – Currently Amended): A method for producing the composition according to claim 1, comprising:

placing ~~a~~the very low water-soluble drug and ~~a~~the porous silicon material in a pressure-resistant vessel;

maintaining the vessel at a temperature at which carbon dioxide is in a supercritical or subcritical state;

filling the vessel with carbon dioxide so as to attain a pressure such that the carbon dioxide assumes the form of a supercritical or subcritical fluid;

treating the drug and the porous silicon material with the supercritical or subcritical carbon dioxide fluid; and

discharging the carbon dioxide fluid from the vessel and collecting the resultant composition;

~~wherein:~~

~~the porous material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of  $\pm$  40% of the average pore diameter accounts for 60% or more of a volume of all the pores of the material, and having an X-ray diffraction pattern including one or more peaks at a diffraction angle ( $2\theta$ ) corresponding to d of 1 nm or more;~~

~~the porous material has an average pore diameter of 1 to 500 nm; and~~

~~the porous material has a specific surface area of 100 to 1,800 m<sup>2</sup>/g.~~

Claim 20 (Withdrawn): The method according to claim 19, wherein a ratio by weight of the very low water-soluble drug to the supercritical or subcritical carbon dioxide fluid is from 1:1 to 1:1,000,000.

Claim 21 (Withdrawn – Currently Amended): The method according to claim 19, wherein treating the drug and the porous silicon material comprises treating at a temperature of from –40 to 100°C.

Claim 22 (Withdrawn – Currently Amended): The method according to claim 19, wherein treating the drug and the porous silicon material comprises treating at a pressure of from 1 to 50 MPa.

Claim 23 (Withdrawn – Currently Amended): The method according to claim 19, wherein treating the drug and the porous silicon material comprises treating for a period of from one minute to 24 hours.